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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/626,582	07/25/2003	Andrew M. Kuhn	P-5802	9537

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DAVID W. HIGHET, VP AND CHIEF IP COUNSEL
BECTON, DICKINSON AND COMPANY
1 BECTON DRIVE, MC 110
FRANKLIN LAKES, NJ 07417-1880

EXAMINER

WHALEY, PABLO S

ART UNIT

PAPER NUMBER

1631

DATE MAILED: 05/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/626,582	KUHN, ANDREW M.	
	Examiner	Art Unit	
	Pablo Whaley	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 March 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) 1-8 and 19-34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date: _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>4/12/04</u> | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1631

DETAILED ACTION

APPLICANT'S ELECTION

Applicants' election of Group II drawn to Claims 9-18, filed 3/20/2006, is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). The requirement is still deemed proper and is therefore made FINAL. Claims 1-8 and 19-34 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

CLAIMS UNDER EXAMINATION

Claims herein under examination are claims 9-18.

INFORMATION DISCLOSURE STATEMENT

The information disclosure statement filed 4/12/04 has been considered in full.

OBJECTIONS

Claim 9 is objected to because of the following informalities: Claim 9 is grammatically incorrect, and should recite "A computerized method for a system to analyze numerical data...". Appropriate correction is required.

Claim 9 is objected to because of the following informalities: Claim 9 is grammatically incorrect, and should recite "sets of data..." throughout claim 9. Appropriate correction is required.

CLAIM REJECTIONS - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 9-18 are rejected under 35 U.S.C. 101 because these claims are drawn to non-statutory subject matter. Claims 9-18 are directed to a computerized method for analyzing numerical data pertaining to a sample assay, which does not recite either a physical transformation of matter nor a practical application [i.e. concrete, tangible, and useful result]. Instant claim 9 recites steps comprising assigning, correcting, and comparing values. The claimed method steps do not result in a physical transformation of matter. Where a claimed method does not result in a physical transformation of matter, it may be statutory where it recites a concrete, tangible, and useful result (i.e. a practical application). However, no actual, concrete result is recited in the claims, nor is any useful result "produced" in a tangible form useful to one skilled in the art. For these reasons, the claims are not statutory. For an updated discussion of statutory considerations with regard to non-functional descriptive material and computer-related inventions, see the Guidelines for Patent Eligible Subject Matter at 1300 OG 142, Annex IV, Nov. 22, 2005.

CLAIM REJECTIONS - 35 USC § 112, 2nd Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 9-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 9 recites the limitation "including a set of data pertaining to each respective sample" (line 3). It is unclear whether there is one "set of data" pertaining to each sample, or multiple sets of data pertaining to all samples. Clarification is requested.

Claim 9 recites the limitation "correcting...values pertaining to said set of data" (line 8). It is unclear which set of data applicant is referring to, as claim 9 also recites a "set of data pertaining to each respective sample" (line 3). Clarification is requested.

Claim 9 recites the limitation "second correcting...based on whether said plurality of corrected exceeds" (lines 10-11). It is unclear as to the intended meaning of "corrected exceeds." Clarification is requested.

Claim 9 recites the limitation "controlling said system" (line 14). As the specification does not define or fully and completely describe "controlling" for carrying out the intended function, it is unclear as to the metes and bounds intended by applicant for the claimed "controlling" such that one skilled in the art would know which steps this consists of. Clarification is requested.

Claim 10 recites the limitation "values at a beginning of a sequence." It is unclear whether "beginning of a sequence" is referring to position, time, or otherwise. Clarification is requested.

Art Unit: 1631

Claims 12 and 14 recite the limitation "values in relation to an adjacent one of said...numerical values." It is unclear whether applicant is referring to corrected numerical values, respective numerical values, or otherwise. Furthermore, it is unclear whether an "adjacent one" is referring to a position, a numerical value, or otherwise. Clarification is requested.

Claim 15 recites the limitation "combining respective ones." It is unclear whether "ones" is referring to positions, actual numerical values, or otherwise; therefore it is unclear what exactly is being combined. Clarification is requested.

Claim 18 recites the limitation "said corrected plurality of adjusted numerical values." There is lack of antecedent basis for this limitation. Clarification is requested. Claims 11, 13, and 16-17 are rejected as they depend directly or indirectly from claim 9.

CLAIM REJECTIONS - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C.102 that form the basis for the rejections under this section made in this Office action: A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 9-14 are rejected under 35 U.S.C. 102 (b) as being anticipated by Yang et al. (US 6,216,049; Issued: Apr. 10, 2001).

Art Unit: 1631

Yang et al. teach a computerized method and apparatus for analyzing nucleic acid assay readings [Abstract]. Reference claims 1 and 2 explicitly teach the limitations of instant claims 9 and 10. Yang et al. further teach the following aspects of the instantly claimed invention: calculation of an average value based on filtered values [Col. 13, lines 10-17], which is a teaching for a correction value as in instant claim 11; first and second difference values calculated based on adjacent smoothed normalized values (i.e. corrected values) [Ref. Claim 3 and Col. 10, lines 47-62], as in instant claims 12 and 14; and calculating average values and comparing average values to threshold [Ref. Claim 4], as in instant claim 13.

Claims 9-11, 13, 17-18, are rejected under 35 U.S.C. 102 (b) as being anticipated by Kurnik et al. (Sensors and Actuators B, 1999, vol. 60, p.19-26).

Kurnik et al. teach a Mixture of Experts (MOE) algorithm for analyzing numerical data in a non-invasive glucose measurement system. More specifically, Kurnik et al. teach the following aspects of the instantly claimed invention:

- glucose data values assigned numerical values over time [Fig. 2 and Fig. 4], which correlates to assigning numerical values to a plurality of data values as in instant claims 1 and 10.
- Raw data is averaged (i.e. first corrected) [Section 4.1, para. 1]; data is compared to predefined values or thresholds (i.e. first compared); values that exceed threshold are excluded (i.e. second corrected) [p.22, col. 2, paragraph 3], as in instant claims 9 and 13.

Art Unit: 1631

- MOE algorithm applied to the corrected data set and compared to reference blood glucose values [Fig. 4], which correlates to second comparing data as in instant claim 9.
- Indication of whether the blood glucose levels as measured by the MOE system are accurate as compared to predetermined blood glucose levels (i.e. characteristics) [Fig. 3], as in instant claim 9.
- Calculating a calibration signal based on a plurality of numerical values including elapsed time after subject calibrates the device [p.20, col. 2, para. 3], which correlates to a beginning of a sequence as in instant claim 11.
- Blood glucose (BG) input values are weighted and assigned respective time values [p. 21, Equations (6) and (7)], as in instant claim 17.
- Corrected values that exceed threshold are excluded [p.22, col. 2, paragraph 3], which correlates to a report of whether corrected numerical values exceed a threshold as in instant claim 18.

PRIOR ART MADE OF RECORD

The prior art made of record and not relied upon which is considered pertinent to applicant's disclosure is:

Tseng et al. (Nucleic Acids Research, 2001, Vol. 29, No. 12, p. 2549-2557)

Altschul et al. (Nucleic Acids Research, 1997, Vol. 25, No. 17, p. 3389-3402)

Art Unit: 1631

CONCLUSION

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pablo Whaley whose telephone number is (571)272-4425. The examiner can normally be reached on 9:30am - 6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached at 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Pablo S. Whaley

Patent Examiner
Art Unit 1631
Office: 571-272-4425

MARJORIE A. MORAN
PRIMARY EXAMINER

Marjorie A. Moran
5/30/06